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SUMMARY
510(k) NUMBER: K052297

POREX SURGICAL ELECTROSURGICAL NEEDLE

SUBMITTER

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265-1017
Tel: (678) 479-1610, Fax: (678)423-1435

CONTACT

Eric V. Hohenstein
Vice President, Special Developmental Projects
Tel: (678) 479-1610 / (323) 876-3767
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PROPRIETARY NAME: Porex Electrosurgery Needle

COMMON NAME: Microdissection Needle, Electrosurgical Needle

DEVICE CLASSIFICATION

DEVICE NAME	CLASS NO.	CLASS	REG NO.
Device, Electrosurgical, cutting & coagulation & accessories	JOS	2	878.4400

IDENTIFICATION OF EQUIVALENT DEVICE

Porex Surgical, Inc. Electrosurgery Needles are substantially equivalent to the following predicate devices in their intended use, material, design, and surgical procedure:

Colorado MicroDissection Needle (K000348)

Megadyne Electrode, Electrosurgery (K903302)

Valleylab Coated Electrodes (K962044)

K052297

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DESCRIPTION

The Porex Surgical, Inc. Electrosurgery Needle is an electrosurgical electrode for use with monopolar electrosurgical accessories (cautery handpieces). It is constructed of a tungsten tip held by a gold plated stainless shaft/sleeve. The electrode shaft has two layers of insulation.

INTENDED USE

The Porex Surgical, Inc. Electrosurgery Needle is an electrosurgical electrode used for cutting, dissecting and cauterizing soft tissue by use of high-frequency electrical current.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Porex Surgical Inc.
c/o Mr. Eric V. Hohenstein
V.P., Special Developmental Projects
15 Dart Road
Newnan, Georgia 30265-1017

Re: K052297
Trade/Device Name: Porex Electrosurgery Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, JOS
Dated: March 6, 2006
Received: March 8, 2006

Dear Mr. Hohenstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

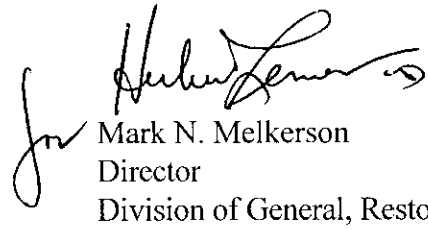
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052297

Device Name: Porex Electrosurgery Needle

Indications For Use:

The Porex Electrosurgery Needle is an electrosurgery electrode for use in monopolar electrosurgical handpieces. It is a single-use device intended for cutting, dissecting, and cauterizing of soft tissue.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052297